PPA and the Risk of Hemorrhagic Stroke

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PPA and the Risk of Hemorrhagic Stroke Selection Bias

- Basic problems with case and control selection in the conduct of the study render this a failed study.
- <u>Cases</u>
 - 702 cases out of 1717 potential cases (41%)
- Controls
 - 151 telephone numbers called to identify a control (p. 17, final report)
 - Approximately 3 eligibles for each control

Cases and controls differ greatly on demographic characteristics, suggesting very substantial selection bias

Education	Cases (%)	Controls (%)		
College	40	62		
< High School	20	9		

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Use History

Any PPA Exposure Cases -- 3.8 % Controls -- 2.4%

• Assume that prevalence was 4% in the 4200 controls not included. True prevalence in controls would be 3.6%

$$1400 \times 2.4 = 33$$

 $4200 \times .04 = 168$

• Same as cases: Due to select bias of controls -- unknown true prevalence of PPA in controls

Time Period of Use of Drug (Men and Women)

	Cases		Controls	
Within 2 wks of current use	N	%	N	%
First use	8	1.1	5	0.4
Not first use	13	1.9	16	1.2
Prior use	06	0.9	12	0.9
Use 2 wks to 3 days of event	11	1.7	33	2.5
Total use	38	5.4	66	4.8

Why greater use in controls -2 weeks-3days prior to event?

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Sex Differences in Outcome

Any PPA <3 days	Cases	(n=383)	Controls	(n=750)	O.R.
	N	%	N	%	
Women	21	5.5	20	2.7	2.0
	Cases	(n=319)	Controls	(n=626)	
	N	%	N	%	
Men	6	1.9	13	2.1	_

Difference in women cases only

Cough/Cold Only

Any PPA <3 days	Cases		Controls		O.R.
	N	%	N	%	
Women	16	4.2	19	2.5	1.54
Men	6	1.9	13	2.1	0.62

Risk for women, protective for men?

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Small Numbers

• Appetite Suppressant for Women

6 Cases

1 Control

Odds Ratio = 12

• Prior Use in Men

1 Case

8 Control

Odds Ratio = 0.25

Characteristics of Cases

- Consumption of Caffeine: Current Users (first use in 3 days)
 - Cases (9)

10 cups coffee / day

8.5 cups coffee / day

10 glasses soda / day

8 glasses soda / day
6 glasses soda / wk (History of stroke)
1 glass soda / wk (History of stroke)

2 - (0) (Both prior headaches)

- Controls (5)

6 cups / day coffee

6 glasses / day soda

2 cups coffee / day (2)

1 negative / day (cup of tea)

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